EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use

Introductory remarks

Aim of the document

This document needs to be read in conjunction with the following documents:

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.
- European Medicines Agency policy on access to documents (EMA/729522/2016).

This document, which contains guidance for the application of Regulation (EC) No 1049/2001 to documents related to medicinal products for human and veterinary use held by the EMA, is not legally binding. For any document not listed, access will be granted or refused in accordance with the principles outlined in the European Medicines Agency policy on access to documents. It should, therefore, be noted that this document should be considered as a

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“living” document which is aimed at increasing the transparency of the Agency's classification of documents. It will be updated on a continuous basis taking into account further experience, as well as the legal interpretation of Regulation (EC) No 1049/2001 given by the European Court of Justice.

Moreover, the “Guide to information on human medicines evaluated by EMA-What the Agency publishes and when” (EMA/515416/2015) describes the different types of information and documents the Agency publishes for both centrally and non-centrally authorised medicines, as well as the publication time and the location on EMA’s website.

For corporate documents, please refer to the “Output of the European Medicines Agency policy on access to documents non-related to medicinal products for human and veterinary use” (EMA/183710/2016).

This “output” document lists the various document types which may be subject to requests for access to documents related to medicinal products for human and veterinary use. These document types have been classified as follows:

1. Documents or relevant section of documents in relation to product-specific issues
    1.1. Documents related to Committee for Human Medicinal Products/Committee for Veterinary Medicinal Product activities
    1.2. Documents related to Pharmacovigilance Risk Assessment Committee activities
    1.3. Documents related to Committee for Orphan Medicinal Products activities
    1.4. Documents related to Committee for Herbal Medicinal Products activities
    1.5. Documents related to Paediatric Committee activities
    1.6. Documents related to Committee for Advanced Therapies activities
    1.7. Documents related to advice from specialised expertise
2. Documents in relation to general scientific issues, organisational and operational aspects
3. Documents prepared by EMA in the context of the Agency’s transparency activities
4. Documents submitted by applicants and marketing authorisation holders
5. Other documents

Furthermore, this document addresses the disclosure of names of individuals involved in an EMA activity and contained in EMA documents.

Abbreviations

BWP:	Biologics Working Party
CAPs:	Centrally Authorised Products
CAT:	Committee for Advanced Therapies
CHMP:	Committee for Human Medicinal Products
CMDh:	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
COMP:	Committee for Orphan Medicinal Products
CVMP:	Committee for Veterinary Medicinal Products
EMA:	European Medicines Agency
EPAR:	European Public Assessment Report
EPMAR:	European Public MRL Assessment Report
HMPC:	Committee for Herbal Medicinal Products
LoQs:	List of Questions
LoOIs:	List of Outstanding Issues
MA:	Marketing Authorisation
MAH:	Marketing Authorisation Holder
MRL:	Maximum Residue Limit
NAPs:	Nationally Authorised Products
Non-R:	Non-Releasable
PASS:	Post-authorisation Safety Study
PDCO:	Paediatric Committee

PIP:	Paediatric Investigation Plan
PRAC:	Pharmacovigilance Risk Assessment Committee
R:	Releasable
RSI:	Request for Supplementary Information
PSURs:	Periodic Safety Update Reports
SAG:	Scientific Advisory Group

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1. Documents or relevant section of documents in relation to product-specific issues						
1.1 Documents related to CHMP/CVMP activities						
CHMP/CVMP Opinion (centralised procedures (CAPs) , arbitration/ referral procedures (CAPs and NAPs), as well as pharmacovigilance procedures (CAPs and NAPs)	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal), or prior to Commission Decision on the Committee Opinion on the outcome of the arbitration/referral procedure	No	Art. 4.3. 1st §		Not applicable
		R • once Commission Decision granting or refusing the MA/variation to the MA, or once Commission	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		Decision on the Committee Opinion on the outcome of the arbitration/ referral procedure is available, • or upon finalisation of the procedure related to the annual Decision of the Commission, • or upon availability of Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal				
CHMP/CVMP Assessment Report centralised procedures (CAPs) , arbitration/ referral procedures (CAPs and NAPs), as well as pharmacovigilance procedures (CAPs and NAPs)	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal), or prior to Commission Decision on the Committee Opinion on the outcome of the arbitration/referral procedure				
		R • once Commission Decision granting or refusing the MA/variation to the MA, or once Commission Decision on the Committee Opinion on the outcome of the arbitration/ referral procedure	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		is available, • or upon finalisation of the procedure related to the annual Decision of the Commission, • or upon availability of Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal				
(Co)-Rapporteur Assessment Report **Written comments from CHMP/CVMP Members** (including comments received in the context of the	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
peer review exercise) **LoQs, LoOIs and RSIs**		(or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal), or prior to Commission Decision on the Committee Opinion on the outcome of the arbitration/referral procedure (where relevant) R • once Commission Decision granting or refusing the MA/variation to the MA, or once Commission Decision on the Committee Opinion on the outcome of	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		the arbitration/ referral procedure (where relevant) is available, • or upon finalisation of the procedure related to the annual Decision of the Commission, • or upon availability of Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal				
Agendas and minutes of CHMP/CVMP meetings[8]	No	Agendas /minutes since December 2013: published on EMA	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		website				
		Agendas/minutes prior to December 2013: R	Yes	Not applicable	Not applicable	Yes
Tables of Conclusions / Decisions of CHMP meetings	No	Non-R for concerned medicinal product prior to Commission Decision granting or refusing the MA/variation to the MA (or CHMP Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal), or prior to Commission Decision on the CHMP Opinion on the outcome of the arbitration/referral procedure	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		R for concerned medicinal product • once Commission Decision granting or refusing the MA/variation to the MA, or once Commission Decision on the CHMP Opinion on the outcome of the arbitration/ referral procedure is available, • or upon finalisation of the procedure related to the annual Decision of the Commission, • or upon availability of Committee Opinion if there is no subsequent Commission Decision, or	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal				
Agendas of CHMP/CVMP Working Party[9] meetings **Tables of Conclusions/Decisions of CHMP Working Party meetings** **Minutes of CHMP/CVMP Working Party meetings**	No	Non-R for concerned medicinal product prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		R for concerned medicinal product once Commission Decision granting or refusing the MA/variation to the MA is available (or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Activities relating to MRL setting: CVMP Opinion and EPMAR	No	Non-R prior to adoption of Commission Regulation on MRL for the concerned substance	No	Art. 4.2. 1st indent		Not applicable
		Published on EMA website after adoption of Commission Regulation on MRL for the concerned substance	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Activities relating to MRL setting (CVMP Assessment Report, (Co)-Rapporteur Assessment Report, written comments from CVMP Members, LoQs, advice from specialised expertise (either in the context of Working Parties, SAGs, *ad hoc* Expert Groups, or in the context of individual advice provided), time schedules for applications)	No	Non-R prior to Commission Decision granting or refusing the MA for a veterinary medicinal product containing the relevant active substance for use in a species to which the MRL evaluation relates	No	Art 4.2. 1st indent		Not applicable
		R once Commission Decision granting or refusing the MA for a veterinary medicinal product containing the relevant active substance for use in a species to which the MRL evaluation relates is available	Yes	Not applicable	Not applicable	Yes
GXP (GMP, GCP, GLP, PhV) Inspection Reports – inspections requested by EMA scientific committees and coordinated by EMA	No, once final and received by EMA	Non-R	No	Art.4.2. 3rd indent		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
GXP (GMP, GCP, GLP, PhV) Inspection Reports – inspections carried out by NCAs under their national inspection programmes	Yes	Non-R	No	Art. 4.2. 3rd indent		Not applicable
GXP (GMP, GCP, GLP, PhV) Inspection Reports –inspections conducted by third parties (non-EU countries or international organisations)	Yes	Non-R	No	Art. 4.2. 3rd indent		Not applicable
Scientific Advice/Protocol Assistance Final Letters **Scientific Advice/Protocol Assistance Coordinators' Reports** **PRIME requests** **MUMS (Minor Use and Minor Species) designations for veterinary medicines**	No	Non-R prior to the submission of the MA application/variation application introducing the indication/additional population to which the scientific advice for the concerned product relates	No	Art. 4.2. 1st indent		Not applicable
		Non-R from submission of the MA application/variation application and prior to Commission Decision	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		granting or refusing the MA/variation to the MA introducing the indication/additional population to which the scientific advice for the concerned product relates (or company's letter notifying the withdrawal)				
		R once Commission Decision is available granting or refusing the MA/variation to the MA introducing the indication/additional population to which the scientific advice for the concerned product relates (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.2 Documents related to PRAC activities						
PRAC Recommendation on pharmacovigilance referrals including temporary measures (CAPs and NAPs)	No	Non-R prior to Commission Decision on the CHMP Opinion/CMD(h) position (the latter in case of absence of consensus) Non-R prior to CMD(h) position (in case of consensus)	No	Art. 4.3. 1st §		Not applicable
		R • once Commission Decision on the CHMP Opinion/CMD(h) position (the latter in case of absence of consensus) is available, • or upon availability of CMD(h) position (in case of consensus)	Yes	Not applicable	Not applicable	Yes
PRAC Recommendation on PSUR assessment	No	***For recommendations to vary, suspend or***	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
and PASS results assessment (CAPs and NAPs)		***revoke the MA:*** Non-R prior to Commission Decision on the CHMP Opinion (or CHMP Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal) Non-R prior to Commission Decision on the CMD(h) position (in case of absence of consensus) Non-R prior to CMD(h) position (in case of consensus) ***For recommendations to maintain the MA:*** Non-R until availability of the PRAC Recommendation				
		For recommendations to vary, suspend or revoke the MA:	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		R • once Commission Decision on the CHMP Opinion is available, • once Commission Decision on the CMD(h) position is available (in case of absence of consensus) • once CMD(h) position is available (in case of consensus) ***For recommendations to maintain the MA:*** R after adoption of the PRAC Recommendation				
PRAC Recommendation on signals (CAPs and NAPs)	No	Non-R prior to adoption of the PRAC Recommendation	No	Art. 4.3. 1st §		Not applicable
		Published on EMA website after PRAC adoption (if no update of the product	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		information is required) Published on EMA website after CHMP adoption (if update of the product information is required)				
PRAC Advice on risk management plans for products in the pre-authorisation phase (CAPs)	No	Non-R prior to Commission Decision granting or refusing the MA, or company's letter notifying the withdrawal	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the MA is available, or company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	Yes
PRAC Advice on risk management plans for authorised products, Type II safety variations, renewals, conditional renewals, annual reassessments	No	Non-R prior to Commission Decision on the variation to the MA, the renewal or annual reassessment (or Committee Opinion if there is no subsequent Commission Decision, or	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		company's letter notifying the withdrawal)				
		R once Commission Decision on the variation to the MA, the renewal or annual reassessment is available, or upon availability of the Committee Opinion if there is no subsequent Commission Decision, or upon finalisation of the procedure related to the annual Decision of the Commission, or upon availability of company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	Yes
PRAC Advice on inspection requests and results (CAPs and NAPs)	No	Non-R	No	Art.4.2. 3rd indent		Not applicable
PRAC Advice on Type II variations, renewals, conditional renewals, annual-reassessments	No	Non-R prior to Commission Decision on the variation to the MA, the renewal or	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		annual reassessment (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)				
		R once Commission Decision on the variation to the MA, the renewal or annual reassessment is available, or upon availability of the Committee Opinion if there is no subsequent Commission Decision, or upon finalisation of the procedure related to the annual Decision of the Commission, or upon availability of company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	Yes
PRAC Advice on safety issues discussed at the request of a Member State (NAPs)	Yes	Non-R prior to finalisation of the regulatory procedure at national level	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		R after finalisation of the regulatory procedure at national level	Yes	Not applicable	Not applicable	Yes
PRAC endorsement / refusal of PASS protocol (CAPs and NAPs)	No	Non-R prior to adoption of PRAC outcome letter (or upon receipt of company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R after adoption of the PRAC outcome letter (or upon receipt of company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
PRAC Assessment Report (for CAPs, CAPS / NAPs or NAPs, for all PRAC procedures)	No	Non-R prior to finalisation of the regulatory procedure (see above for the concerned PRAC procedures)	No	Art. 4.3. 1st §		Not applicable
		R after finalisation of the regulatory procedure (see	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		above for the concerned PRAC procedures)				
PRAC (Co)-Rapporteur Assessment Report **Written comments from PRAC members** **LoQs, LoOIs and RSIs** **(for CAPs, CAPS/NAPs or NAPs, for all PRAC procedures)**	No	Non-R prior to finalisation of the regulatory procedure (see above for the concerned PRAC procedures)	No	Art. 4.3. 1st §		Not applicable
		R after finalisation of the regulatory procedure (see above for the concerned PRAC procedures)	Yes	Not applicable	Not applicable	Yes
Agendas and minutes of PRAC meetings[8]	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Tables of Conclusions/Decisions of PRAC meetings	No	Non-R for concerned medicinal product prior to finalisation of the regulatory procedure (see above for the concerned PRAC procedures)	No	Art. 4.3. 1st §		Not applicable
		R after finalisation of the regulatory procedure (see above for the concerned	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		PRAC procedures)				

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.3 Documents related to COMP activities						
Opinion on Orphan Designation (Opinion page only)	No	Non-R prior to Commission Decision granting or refusing the designation (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the designation is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
COMP Summary Report (orphan designation) **Written comments from COMP Members** **LoQs**	No	Non-R prior to Commission Decision granting or refusing the designation (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the designation is available (or	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		company's letter notifying the withdrawal)				
Opinion on review of designation criteria at time of MA/new orphan indication **Summary report of review of designation criteria at time of MA/new orphan indication**	No	Non-R prior to Commission Decision granting or refusing the orphan MA/new orphan indication (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision is available for concerned medicinal product granting or refusing the orphan MA/new orphan indication (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Agendas and minutes of COMP meetings[8]	No	Agendas since October 2012 and minutes since July 2012: published on EMA website	Yes	Not applicable	Not applicable	No
		Agendas and minutes prior to these dates: R	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.4 Documents related to HMPC activities: prepared by HMPC Rapporteurs – HMPC Experts during the scientific assessment process for the establishment of Community herbal monographs and Community list entries						
HMPC Opinions	No	Published on EMA website after adoption by HMPC	Yes	Not applicable	Not applicable	No
HMPC Assessment Report	No	Non-R before adoption by HMPC	No	Art. 4.3. 1st §		Not applicable
		R after adoption by HMPC	Yes	Not applicable	Not applicable	Yes
Bibliographic references (supporting HMPC assessment reports)	No	R	No[10]	Not applicable	Not applicable	Not applicable
Overviews of comments received during public consultation period	No	Non-R before adoption by HMPC	No	Art. 4.3. 1st §		Not applicable
Community herbal monographs and list entries (submitted by interested parties in accordance with the ''HMPC Procedure on management of proposals from interested parties for Community list entries and Community herbal monographs' (EMEA/HMPC/328575/2007))	Yes	Non-R before the procedure establishing the HMPC monograph is finalised/the list entry is published by the European Commission	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		Published on EMA website after the procedure establishing the HMPC monograph is finalised/the list entry is published by the European Commission	Yes	Not applicable	Not applicable	No
Agendas and minutes of HMPC meetings[8]	No	Agendas and minutes since September 2013: published on EMA website	Yes	Not applicable	Not applicable	No
		Agendas and minutes prior to this date: R	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.5 Documents related to PDCO activities						
EMA Decisions on PIP, PIP modification and product-specific waiver (excluding the Summary Report part, see below)	No	Published on EMA website once the EMA Decision is available	Yes	Not applicable	Not applicable	No
EMA Decisions on class waivers	No	Published on EMA website once the EMA Decision is available	Yes	Not applicable	Not applicable	No
PDCO Compliance Opinion	No	Non-R prior to the adoption of the PDCO Opinion	No	Art. 4.3. 1st §		Not applicable
	No	R once the PDCO Opinion is available	Yes	Not applicable	Not applicable	No
EMA/PDCO Summary Reports on applications on PIPs, PIP modification(s)	No	Non-R prior to the EMA Decision on PIP/PIP modification(s) for the concerned medicinal product/active substance	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		R once the EMA Decision on PIP/PIP modification(s) is available for the concerned medicinal product/active substance and PIP/PIP modification(s) is completed or company's letter notifying the withdrawal of the PIP/PIP modification(s) has been received	Yes	Not applicable	Not applicable	Yes
• **EMA/PDCO Summary Reports on applications of product specific full waivers** • **EMA/PDCO Summary Reports on applications on PIPs, PIP modifications resulting in granting product specific full waivers**	No	Non-R prior to EMA Decision on the granting or refusing of a product specific waiver is available for the concerned medicinal product/active substance	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
	No	R once the EMA Decision on the granting or refusing a product specific waiver is available for the concerned medicinal product/active substance or company's letter notifying the withdrawal of the full waiver has been received	Yes	Not applicable	Not applicable	Yes
EMA/PDCO Compliance Report	No	Non-R prior to the adoption of the PDCO opinion on compliance for the concerned medicinal product/active substance.	No	Art. 4.3. 1st §		Not applicable
		R once PDCO opinion on compliance for the concerned medicinal product/active substance has been adopted.	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Public Summary of the proposed evaluation of the PIP/waiver/modification procedure	No	Published on EMA website once EMA Decision is available for concerned PIP/waiver	Yes	Not applicable	Not applicable	No
Agendas and minutes of PDCO meetings[8]	No	Agendas and minutes since June 2012: published on EMA website	Yes	Not applicable	Not applicable	No
		Agendas and minutes prior to these dates: R	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.6 Documents related to CAT activities						
CAT Draft Opinion	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
CAT Assessment Report	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		MA/variation to the MA is available (or company's letter notifying the withdrawal)				
(Co)-Rapporteur Assessment Report **Written comments from CAT Members** (including comments received in the context of the peer review exercise) **LoQs and LoOIs**	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Agendas and minutes of CAT meetings[8]	No	Agendas and minutes since December 2013: published on EMA website	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		Agendas and minutes prior to this date: R	Yes	Not applicable	Not applicable	Yes
Tables of Conclusions / Decisions of CAT meetings	No	Non-R prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R for concerned medicinal product once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Agendas of CAT Working Party meetings **Tables of Conclusions / Decisions of CAT Working Party meetings**	No	Non-R prior to Commission Decision for concerned medicinal product granting or refusing the	No	Art. 4.3. 1st §		Not applicable

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Minutes of CAT Working Party meetings		MA/variation to the MA (or company's letter notifying the withdrawal)				
		R for concerned medicinal product once Commission Decision is available granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Documents related to ATMP Certification (Request for supplementary information for ATMP Certification, CAT certification evaluation report (D90), CAT Opinion on certification, EMA Certificate for ATMP certification or EMA advisory letter refusing ATMP certification)	No	Non-R prior to Commission Decision for concerned medicinal product granting or refusing the MA application (or company's letter notifying the withdrawal)	No	Art. 4.2. 1st indent		Not applicable
		R once Commission Decision is available for concerned medicinal product granting or	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		refusing the MA (or company's letter notifying the withdrawal)				
Documents related to ATMP Classification (CAT Recommendation on classification as ATMP, List of questions for the ATMP classification procedure)	No	Non-R prior to end of the procedure at Day 60	No	Art 4.3. 1st §		Not applicable
		R after the procedure at Day 60	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
1.7 Documents related to advice from Specialised Expertise						
Advice from Specialised Expertise (either in the context of Working Parties (e.g. BWP), SAGs, *ad hoc* Expert Groups, or in the context of individual advice provided), covering centralised procedures (CAPs), arbitration/ referral procedures (CAPs and NAPs, as well as pharmacovigilance procedures (CAPs and NAPs) **Agendas and minutes of SAG and *ad hoc* Expert Group meetings**	No	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the MA/variation to the MA is available (or Committee Opinion if there is no subsequent Commission Decision/the procedure is subject to the annual decision of the Commission, or	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)				

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
2. Documents or relevant section of documents in relation to general scientific issues, organisational and operational aspects						
Agendas and minutes of CHMP/CVMP/COMP/ HMPC/PDCO/CAT/PRAC meetings[8]	No	Published on EMA website as specified before for the various Committees	Yes	Not applicable	Not applicable	No
		R prior to first publication of Committees' agendas and minutes as specified before for the various Committees	Yes	Not applicable	Not applicable	Yes
Tables of Conclusions/Decisions of CHMP/ COMP/ HMPC/PDCO/CAT/PRAC meetings	No	R	Yes	Not applicable	Not applicable	Yes
Agendas and minutes of Working Party meetings	No	R	Yes	Not applicable	Not applicable	Yes
Tables of Conclusions/Decisions of Working Party meetings	No	R	Yes	Not applicable	Not applicable	Yes
Work plans of the EMA Scientific Committees	No	Published on EMA website once discussions	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
and Working Parties		are finalised at the respective EMA Scientific Committee				
Rules of Procedure and mandates or equivalent documents of the EMA Scientific Committees and their Working Parties	No	Published on EMA website once discussions are finalised at the respective EMA Scientific Committee and, where required, subsequent adoption by the European Commission and/or the Management Board has been obtained	Yes	Not applicable	Not applicable	No
Guidelines and other related documents (including concept papers, reflection papers, draft guidelines and final guidelines)[11]	No	Published on EMA website once discussions at the respective EMA Scientific Committee or the Inspections Working Group are finalised either resulting in a release for consultation or the final adoption	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Guidelines and other related documents (including concept papers, reflection papers, draft guidelines and final guidelines)[11] – previous versions not available on EMA's website	No	R	Yes	Not applicable	Not applicable	No
List of medicinal products under additional monitoring	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Medical literature monitoring: substance and herbal substance groups	No	Published on EMA website	Yes	Not applicable	Not applicable	No
List of Union reference dates and frequency of submission of PSURs for CAPs and NAPs	No	R once adopted by the CHMP and the CMDh following consultation with the PRAC	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
3. Documents prepared by the EMA in the context of the Agency's transparency initiatives						
CHMP/CVMP/COMP/HMPC/PDCO/CAT/PRAC Press Releases/Monthly Reports/Meeting Reports	No	Published on EMA website after embargo date and time	Yes	Not applicable	Not applicable	No
Product specific Press Releases/Public Statements/Q&A documents	No	Published on EMA website after embargo date and time	Yes	Not applicable	Not applicable	No
Summaries of CHMP/CVMP Opinion (both pre- and post-authorisation)	No	Published on EMA website after embargo date and time	Yes	Not applicable	Not applicable	No
Summaries of PRAC recommendations	No	Published on EMA website after embargo date and time	Yes	Not applicable	Not applicable	No
EPARs **EPAR summaries** **EPAR summary updates**	No	Published on EMA website once Commission Decision is available (or Committee Opinion if there is no subsequent Commission Decision)	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Withdrawal Assessment Reports (excl. MRLs)	No	Published on EMA website once company's letter notifying the withdrawal is available and Withdrawal Assessment Report is finalised (approximately 3 months after company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	No
Public Summary of Opinion on Orphan Designation **Public Summary of review of orphan designation at time of MA**	No	Published on EMA website once Commission Decision on Orphan Designation is available	Yes	Not applicable	Not applicable	No
Summary of CAT Scientific Recommendation on ATMP Classification	No	Published on EMA website once the CAT Recommendation has been adopted	Yes	Not applicable	Not applicable	No
HMPC Assessment Report Summary for the Public	No	Published on EMA website after adoption by the HMPC	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
PIP and Waiver Decision / Public Summary of the proposed evaluation of the PIP/waiver	No	Published on EMA website once EMA Decision is available for concerned PIP/waiver	Yes	Not applicable	Not applicable	No
Annual Report on deferrals of PIP measures	No	Published on EMA website	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
4. Documents submitted by applicants and MAHs						
Marketing Authorisation dossier / updates and changes to the Marketing Authorisation dossier including pre-authorisation applications (such as Scientific Advice requests, MRL applications, Innovation Task Force documents, Clinical Study Reports (CSRs) etc.), or pharmacovigilance post-authorisation procedures (centralised procedures (CAPs) , arbitration/ referral procedures (CAPs and NAPs, and pharmacovigilance procedures (CAPs and NAPs)	Yes	Non-R prior to Commission Decision (or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision is available (or Committee Opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
5. Other Documents						
Documents held by the EMA, for which the EMA is not the originator, and falling within the scope of CMD(h)/CMD(v) activities	Yes and always requiring third-party consultation prior to disclosure	Non-R until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.[12]		Yes
Documents held by the EMA, for which the EMA is not the originator, and falling within the scope of PRAC activities for non-CAPs	Yes and always requiring third-party consultation prior to disclosure	Non-R until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.		Yes
Documents held by the EMA, for which the EMA is not the originator, and falling within the scope of the Inspections Group activities for non-CAPs	Yes and always requiring third-party consultation prior to disclosure	Non-R until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.		Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Documents in the framework of Sampling and Testing (product related and non-product related documents)	No	Non-R	No	Art. 4.1.(a) 3rd indent		Not applicable
Reports linked to the EDQM Agreement as well as EDQM documents	Yes, and always requiring third-party consultation prior to disclosure	Non-R until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.1.(a) 3rd indent		Yes
Documents held by the EMA in the context of international cooperation (e.g. Third Party bilateral agreements)	Yes	Non-R	No	Art. 4.1.(a) 3rd indent		Not applicable
Documents held by EMA in the context of Mutual Recognition Agreements (Assessment Reports of Regulatory Agencies, Annual Reports)	Two situations are possible: In those cases where there is a joint ownership, consultation	Non-R (in both situations), until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.1.(a) 3rd indent		Yes

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
	will take place as per the joint ownership agreement • Where there is no specific provision, third party consultation will take place					

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
6. Disclosure of names of individuals involved in an EMA activity and contained in EMA documents						
Names of CHMP/CVMP/PRAC/COMP/HMPC/PDCO/CAT and Working Party members (composition of Committee/Working Party only)	Not applicable	Published on EMA website	Yes	Not applicable	Not applicable	No
Names of SAG core members (composition of SAG core group only)	Not applicable	Published on EMA website	Yes	Not applicable	Not applicable	No
Names of CHMP/CVMP and PRAC (Co)-Rapporteurs involved in pre-authorisation activities, as well as in arbitration and referral procedures **Names of scientific committee peer reviewers**	Not applicable	Non-R prior to Commission Decision granting or refusing the MA, or prior to Commission Decision on the Committee Opinion on the outcome of the arbitration/referral procedure, or prior to company's letter notifying the withdrawal	No	Art. 4.3. 1st §		Not applicable
		R once Commission Decision granting or refusing the MA, or on the Committee Opinion on the outcome of the arbitration/referral	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		procedure is available, or upon availability of the company's letter notifying the withdrawal				
Names of CHMP/CVMP members expressing a divergent position in the Annexes of the Committee's opinion	Not applicable	Non-R prior to outcome of re-examination, where applicable	No	Art. 4.3. 1st §		Not applicable
		Published on EMA website at time of Opinion unless re-examination has been requested. In case of re-examination the names will be published at the time of the outcome of the re-examination, or upon availability of the company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	No
Names of CHMP/CVMP and PRAC (Co)-Rapporteurs involved in post-authorisation activities	Not applicable	Published on EMA website	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
Names of SAG additional members and *ad hoc* Expert Group members involved in the assessment process of a specific medicinal product	Not applicable	Non-R prior to Commission Decision granting or refusing the MA/variation to the MA, or prior to Commission Decision on the Committee Opinion on the outcome of the referral, or prior to company's letter notifying the withdrawal	No	Art. 4.3. 1st §	Not applicable	No
		R once Commission Decision granting or refusing the MA/variation to the MA is available, or on the Committee Opinion on the outcome of the referral is available, or upon availability of the company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	No
Names of Inspectors	Not applicable	Non-R	No	Art. 4.2. 3rd	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
				indent		
Names of CHMP/CVMP and PRAC assessors, part of the CHMP/CVMP (Co)-Rapporteur team (pre- and post-authorisation)	Yes[13]	Non-R	No	Art 4.5	Not applicable	Not applicable
Names of Rapporteur(s), peer-reviewers and assessors involved in the establishment of Community herbal monographs and Community list entries	Not applicable	Non-R before adoption by HMPC of the Assessment Report	No	Art. 4.3. 1st §	Not applicable	Not applicable
		R after adoption by HMPC of the Assessment Report	Yes	Not applicable	Not applicable	No
Names of HMPC (Co)-Rapporteurs and HMPC peer-reviewers involved in arbitration and referral procedures	Not applicable	Non-R prior to Commission Decision granting or refusing the MA, or prior to Commission Decision on the Committee Opinion on the outcome of the arbitration/referral procedure, orprior to company's letter notifying the withdrawal	No	Art. 4.3. 1st §	Not applicable	Not applicable
		R once Commission Decision granting or	Yes	Not applicable	Not applicable	No

Document type[1]	Third-party document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
		refusing the MA, or on the Committee Opinion on the outcome of the arbitration/referral procedure is available, or upon availability of the company's letter notifying the withdrawal				
Names of Rapporteur(s) and other scientific experts involved in the establishment of Guidelines and other related documents (including concept papers, reflection papers, draft Guidelines and final Guidelines[11]-previous versions not available on EMA's website)	Not applicable	Non-R before adoption by the relevant Committee of the scientific Guideline	No	Art. 4.3. 1st §	Not applicable	Not applicable
		R after adoption by the relevant Committee of the scientific Guideline	Yes	Not applicable	Not applicable	No
Names of EMA Staff involved in pre- and post-authorisation activities not listed on EMA's website	Not applicable	Non-R	No	Art. 4.1.(b)	Not applicable	Yes

Footnotes

1 Refers to any document the EMA produces, receives or has in its possession.

2 Means any natural or legal person, or any entity outside the EMA, including the Member States, other Community or non-Community Institutions and Bodies, and third countries. Either "Yes" or "No" to be filled in. "Yes" may/shall lead to a consultation exercise with the third party (cfr. policy for further details) with a view to assessing whether an exception listed in Article 4 of Regulation (EC) No 1049/2011. (see also footnote 14) is applicable, unless it is clear that the document shall or shall not be disclosed.

[3] All documents classified as Releasable (R) or Non-Releasable (NON-R). Releasable (R) are the documents that are either published on the Agency's website or that can be released in line with the European Medicines Agency policy on access to documents and the provisions of Regulation (EC) No 1049/2001. Non-Releasable (NON-R) are the documents that cannot be released in line with the European Medicines Agency policy on access to documents and the provisions of Regulation (EC) No 1049/2001.

[4] Either access to be granted (Yes) or to be refused (No); in case of third-party consultation the granting or not of access will depend on the outcome of such consultation.

[5] Only to be filled in if access to EMA documents is refused by virtue of application of one of the exceptions mentioned in Article 4 of Regulation (EC) No 1049/2001, i.e. by referring to:

Article 4.1.(a)
The Agency shall refuse access to a document where disclosure would undermine the protection of the public interest as regards public security, defence and military matters, international relations, the financial, monetary or economic policy of the EU or a Member State.

Article 4.1.(b)
The Agency shall refuse access to a document where disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data.

Article 4.2. 1st indent
The Agency shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

Article 4.2. 2nd indent
The Agency shall refuse access to a document where disclosure would undermine the protection of court proceedings and legal advice.

Article 4.2. 3rd indent
The Agency shall refuse access to a document where disclosure would undermine the protection of the purpose of inspections, investigations and audits.

Article 4.3. 1st paragraph
Access to a document, produced, received or in possession of the Agency shall be refused if disclosure of the document would seriously undermine the decision-making process.

Article 4.3. 2nd paragraph
Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the Agency shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the Agency's decision-making process.

[6] Additional justification to be provided in order to further elaborate on the rationale for not providing access as per the reference to the exceptions mentioned in Article 4. Such additional justification will be included in the document on an ongoing basis once more experience is obtained.

[7] Redaction of EMA documents will be carried out to remove any reference to commercial confidential information or to personal data.

[8] See "Principles for publication of agendas and minutes of EMA scientific committees (EMA/555647/2013).

[9] This includes the QRD (Quality Review of Documents) and invented Name Review Group meetings, where relevant.

[10] Copies of bibliographic data protected by copyright, according to Article 16 of Regulation (EC) No 1049/2001, cannot directly be provided by the EMA to the public.

[11] As defined in the 'Procedure for EU guidelines and related documents within the pharmaceutical legislative framework' (EMEA/P/24143/2004 Rev. 1 corr).

[12] In line with Regulation (EC) No 1049/2001 a Member State may request not to disclose without its prior agreement.

[13] A third-party consultation has been undertaken resulting in the Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency (Doc. Ref.: EMA/150487/2010).